

Voluntary Submission of Data and Information by Drug Manufacturers Regarding the  
January 1, 2004 Payment Changes for Medicare Part B Drugs

The Medicare Prescription Drug, Improvement, and Modernization Act (DIMA) of 2003 reforms payments for currently covered Medicare Part B drugs, including drugs furnished incident to a physician's service, drugs furnished under the durable medical equipment (DME) benefit, oral anti-cancer drugs, and oral immunosuppressive drugs. While drug administration payments are increasing substantially effective January 1, 2004, payments for many of the drugs are decreasing. However, the new law allows the Centers for Medicare and Medicaid Services (CMS) to make appropriate adjustments to drug payments in some circumstances provided the manufacturer of a drug submits data and information to CMS before January 1, 2004. Any adjustment to the payment for the drug would be effective April 1, 2004. This letter provides details about how manufacturers can submit this data and information to CMS if interested. Note that this letter does not address any aspect of the new Medicare prescription drug benefit.

In general, the law specifies that the CY 2004 payments for Medicare Part B drugs not paid on a cost or prospective payment basis will be based on 85% of the average wholesale price (AWP) determined as of April 1, 2003. The law specifies certain exceptions to this general rule.

1. The following drugs will be paid at 95% of AWP:
  - blood clotting factors;
  - drugs and biologicals that were not available for Medicare payment as of April 1, 2003;
  - pneumococcal, influenza, and hepatitis B vaccines; and,
  - drugs and biologicals furnished in connection with renal dialysis services if separately billed by renal dialysis facilities.
2. Infusion drugs when furnished through a covered item of durable medical equipment (DME) will be paid based on the October 1, 2003 AWP.
3. Drugs contained in the attached Table 1 will be paid based on the percentage of the April 1, 2003 AWP indicated in the table.

The law also creates a payment exceptions process for drugs paid using the general rule of 85% of the April 1, 2003 AWP or the percentage of the April 1, 2003 AWP indicated in Table 1. The manufacturer of a drug may submit data and information supporting the use of a different percentage of the April 1, 2003 AWP. The law specifies that the data and information must be submitted before January 1, 2004 and any new percentage of the April 1, 2003 AWP determined will be effective April 1, 2004. While the data and information must be submitted before January 1, 2004, we will accept data and information supplementing the initial request if received by 5 p.m. EST on January 16, 2004.

In order to assist CMS in making an appropriate adjustment to the payment for a drug, we suggest that manufacturers submit data and information on the average sales price of the drug, as defined for the purpose of this exceptions process in Attachment A. We would consider these data and other information available to us in establishing a payment adjustment. Manufacturers should note that we would base any payment changes only on data and information that we can make available to the public.

The exceptions data and information can be submitted to: Centers for Medicare and Medicaid Services, Department of Health and Human Services, Attention: CMS-1372-IFC, P.O. Box 8013, Baltimore, MD 21244-8013.

**Table 1**  
**Percentage of April 1, 2003 AWP Used to Calculate the 2004 Payment for**  
**Selected Drugs**

<b>Brand Drugs</b>	<b>HCPCS</b>	<b>Percentage of April 1, 2003 AWP</b>
EPOETIN ALFA (PROCRIT)	Q0136	87%
LEUPROLIDE ACETATE (LUPRON)	J9217	81%
GOSERELIN ACETATE (ZOLADEX)	J9202	80%
RITUXIMAB (RITUXAN)	J9310	81%
PACLITAXEL (TAXOL)	J9265	81%
DOCETAXEL (TAXOTERE)	J9170	80%
CARBOPLATIN (PARAPLATIN)	J9045	81%
IRINOTECAN (CAMPTOSAR)	J9206	80%
GEMCITABINE HCL (GEMZAR)	J9201	80%
PAMIDRONATE DISODIUM (AREDIA)	J2430	85%
DOLASETRON MESYLATE (ANZEMET)	J1260	80%
FILGRASTIM (NEUPOGEN) 480mcg	J1441	81%
HYLAN G-F 20 (SYNVISIC)	J7320	82%
MYCOPHENOLATE MOFETIL (CELLCEPT)	J7517	86%
FILGRASTIM (NEUPOGEN) 300mcg	J1440	81%
GRANISETRON HCL (KYTRIL)	J1626	80%
ONDANSETRON (ZOFRAN)	J2405	87%
VINORELBINE TARTATE (NAVELBINE)	J9390	81%

SARGRAMOSTIM (LEUKINE)	J2820	80%
TOPOTECAN (HYCANTIM)	J9350	84%
<b>Generic Drugs</b>		
IPRATROPIUM BROMIDE	J7644	80%
ALBUTEROL SULFATE	J7619	80%
IMMUNE GLOBULIN	J1561 J1563	80%
LEUCOVORIN CALCIUM	J0640	80%
DOXORUBICIN HCL	J9000	80%
DEXAMETHOSONE SODIUM PHOSPHATE	J1100	86%
HEPARIN SODIUM LOCK- FLUSH	J1642	80%
CROMOLYN SODIUM	J7631	80%
ACETYLCYSTEINE	J7608	80%

## **Attachment A: Manufacturer's Average Sale Price Calculation**

For the purpose of the exceptions process, the manufacturer's average sales price for a drug or biological is calculated as the manufacturer's sales to all purchasers in the United States (excluding sales exempted below) for the most recent quarter available divided by the total number of units of such drug or biological sold by the manufacturer in that quarter. The submission should also specify the units used in the calculation (for example, micrograms).

In calculating the manufacturer's average sales price, a manufacturer should include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid program). To the extent that there is a lag in the availability of this information applicable to the quarter, the manufacturer should apply a methodology based on the most recent 12-month period available to estimate costs attributable to these price concessions. The manufacturer should submit a description of the methodology used to estimate these costs.

In calculating the manufacturer's average sales price, a manufacturer should exclude the following sales as defined for the Medicaid best price calculation under section 1827(c)(1)(C)(i) of the Act:

1. sales to the Indian Health Service, the Department of Veterans Affairs, a state home as defined for the purposes of the Medicaid best price calculation, the Department of Defense, the Public Health Service and entities described in section 340(B)(a)(4) of the Public Health Act;
2. sales under the Federal Supply Schedule of the General Services Administration;
3. sales under a State pharmaceutical assistance program; and
4. any depot sales and single award contract sales as defined for the purposes of the Medicaid best price calculation.

A manufacturer should also exclude sales at a nominal charge. Sales at a nominal charge are defined as sales below 10 percent of the average calculated as described above. In other words, after following the methodology described above, sales below 10 percent of the resulting average should be excluded and the average recalculated. The result of this final calculation is the average sales price for the purpose of the exceptions process.